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2020-07

Laukkavirta , M , Nikulainen , V , Blomgren , K & Helmiö , P 2020 , ' Patient Injuries in Treatment of Peripheral Arterial Disease in Finland: Review of National Patient Insurance Charts ' , Annals of Vascular Surgery , vol. 66 , pp. 225-232 . https://doi.org/10.1016/j.avsg.2019.12.003

http://hdl.handle.net/10138/323125
https://doi.org/10.1016/j.avsg.2019.12.003

acceptedVersion

Journal Pre-proof

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PII: S0890-5096(19)31035-0

DOI: https://doi.org/10.1016/j.avsg.2019.12.003

Reference: AVSG 4804

To appear in: *Annals of Vascular Surgery*

Received Date: 2 October 2019

Revised Date: 4 December 2019

Accepted Date: 6 December 2019

Please cite this article as: Laukkavirta M, Nikulainen V, Blomgren K, Helmiö P, Patient Injuries in Treatment of Peripheral Arterial Disease in Finland: Review of National Patient Insurance charts, *Annals of Vascular Surgery* (2020), doi: https://doi.org/10.1016/j.avsg.2019.12.003.

Patient Injuries in Treatment of Peripheral Arterial Disease in Finland: Review of National Patient Insurance charts

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Category: Original article

This work has been previously presented 17th April 2019 in Charing Cross symposium's abstract session in London and the modified abstract has been printed in the symposium's abstract book.

Funding

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

Declarations of interest: None

ABSTRACT (248 words)

Background

Patient injury claim data and insurance records constitute detailed sources of information on patient injuries and their contributing or causal factors. This study aimed to identify the unintended incidents that lead to patient injuries in vascular surgery in the treatment of peripheral arterial disease (PAD) in Finland.

Methods

The records of all accepted patient injury claims involving PAD between 2004 to 2017 inclusive were obtained from the nationwide Finnish Patient Insurance Centre registry and reviewed. Factors contributing to injury were classified by patient care-flow.

Results

Sixty-nine patient injury incidents were identified in 60 treated PAD patients. Sixteen injuries (23.2%) were related to outpatient or preoperative care. Twenty-seven injuries (39.1%) were caused by incidents in performing open or endovascular procedures and 26 injuries (37.7%) were related to postoperative care.

Delay in treatment affected 11 (18.3%) patients. Incidents involving surgical technique were identified in the treatment of 13 (21.7%) patients. Retained foreign material caused injuries to four (6.7%) patients. Five (8.3%) patients suffered from postoperative haemorrhage and eleven (18.3%) from infection damage.

Delay in treatment resulted in two major amputations. Technical problems in bypass operations led to the loss of the bypass graft and to re-operation. Three nerve injuries led to a permanent disability. One (1.7%) patient died due to fatal postoperative bleeding after being discharged from the hospital.

Conclusions

Compensated patient injuries in the treatment of PAD are rare. Injuries occur during all stages of care and are caused both by surgical system procedural failures and common complications.

1. Introduction

Prevention of patient injuries is one of the most important goals for all health care providers. Patient injuries cause significant monetary losses and can have devastating effects to the injured. Much of this could be avoided as many of the injuries are preventable.(1) Patient injury claim data and insurance records constitute detailed sources of information on patient injuries and their contributing or causal factors.(2) Analysis of claims can reveal information about rare events, which are usually not easily detectable in clinical work.(3)

The National Institute of Health and Welfare of Finland recorded 2059 open revascularizations and 2466 endovascular diagnostic and interventional procedures for peripheral arterial disease (PAD) in 2004. By 2017, the respective numbers were 2577 and 3177.(4) During the first decades of 21st century an increase in revascularisation procedures for PAD also occurred in Denmark and the United States.(5, 6)

Graft occlusion, infection, and haemorrhage are common complications after arterial surgery.(7-9) Due to the nature of the illness, it is not always possible to achieve satisfactory treatment results. The types of problems in the treatment of PAD patients can include cardiovascular, respiratory, and renal complications.(10-12) Complications can occur during adequate treatment but may also be caused by adverse events that lead to patient injury.

Only a small number of published research studies exist that concern patient injuries in vascular surgery and PAD. In previous patient injury studies from the United Kingdom (UK) and Sweden, PAD patients have been a major group in vascular surgery that have received compensation.(13, 14) In the UK, 21% of successful claims were related to peripheral vascular disease.(14) In Sweden, 23% of compensated claims involved peripheral vascular disease.(13)

All official health care providers in Finland are mandated to have patient insurance according to the Patient Injuries Act (Potilasvahinkolaki 585/1986).(15) The Patient Insurance Centre (PIC) insures all patients, processes claims, and when the claim is upheld pays compensation

accordingly. Health care professionals are by law obliged to guide patients how to submit a claim to PIC for a suspected patient injury. All health care providers are mandated to provide services of a patient ombudsman. The patient can contact the ombudsman to receive advice and help in making a patient injury claim. PIC does not hold a registry of all suspected complications but only of submitted patient injury claims.(15)

Only cases that fulfil criteria described in the Patient Injuries Act can be compensated by the PIC. The Patient Injuries Act can be applied, if the following preconditions are met: A patient has sustained a bodily injury in connection with medical treatment or health care within the geographical area of Finland while the Patient Injuries Act was in force, i.e. from the 1st May 1987 onwards. The Finnish patient insurance system has no remit to determine the guilty party. Patient Insurance will only cover the extra costs and losses incurred by the patient's injury. Costs and losses that would have been incurred regardless of the patient's injury are not covered by insurance.(15)

Patient injury is usually a result of multiple unfortunate factors.(16) Many failures that lead to patient harm stem from the failures of the system.(17) In order to ascertain the reasons leading to injury, the patient's pathway through the treatment process should be analysed on a systemic basis.

Aims

The aim of this study was to identify specific incidents that led to patient injuries in the treatment of PAD patients in Finland over a 14-year period in order to help prevent such incidents in future.

2. Material and Methods

Study design is a retrospective analysis of Finnish national patient insurance charts involving patient injuries incurred in the treatment of PAD.

Vascular surgery became an independent specialty in Finland in 2004. The records of all accepted patient injury claims in vascular surgery between 1 January 2004 and 31 December 2017 were sought for and obtained from the nationwide PIC registry.(15) The injuries are classified by specialty in PIC registry. Before 2004 vascular surgery related patient injuries were classified with other surgical patient injuries and cannot be identified reliably. The data search involving vascular surgery related patient injuries was performed by PIC. All closed and compensated claims concerning vascular surgery were analysed. Injuries involving PAD were reviewed and evaluated in detail.

A. The PIC compensation criteria for patient injury

Seven compensation criteria or types of injury are: treatment injury, infection injury, accident injury, equipment-related injury, injury arising from damage to treatment premises or the equipment used for the treatment, injury due to incorrect supply of pharmaceuticals, and unreasonable injury. A treatment injury is the most typical injury. A prerequisite for compensation is that an experienced medical professional could have acted differently thereby avoiding the injury. Infection injuries are only compensated if the likelihood of infection preoperatively is considered low (usually under 2%). Unreasonable injury can be compensated even if no fault is found in treatment. This type of injury is a severe injury which is materially disproportionate with the initial situation.(15)

B. Data processing

All medical records, expert assessments, and compensation decisions of the included claims underwent a review by two vascular surgeons. Age, sex, and major comorbidities were recorded, and information on health care providers and institutions was analysed. Types of operations and the need for re-operation were recorded.

For the purposes of this study, incidents that contributed to injury were identified and classified based on the care-flow process of the patient. Outpatient care was defined to have been given

120 before referral to vascular surgeon and preoperative care after referral had been made. One or
121 two significant incidents were identified. The structure of our classification was based on the
122 classification originally presented by Shah(18) and subsequently modified by the authors for a
123 previous study(19).

124 *C. Statistical analysis*

125 These study data are given as categorical variables, frequencies and percentages. No statistical
126 testing was done as no hypothesis was formulated.

127 *D. Ethical considerations*

128 All information regarding patients' identities were excluded from these data. The study protocol
129 and data search were preapproved by both the PIC and by the University of Turku. The PIC is an
130 insurance company and by law is allowed to provide researchers with data from their archives
131 without separate patient consent. As the study data covers all of Finland and a long time period it
132 makes identifying individual patients or hospitals highly unlikely. No separate approval for this
133 study was required from the Ethics committee as this was a retrospective analysis of insurance
134 charts.

135

136 ## 3. **Results**

137 During the 14-year study period, 6.9% of patient injury claims concerning PAD led to
138 compensation. Altogether 60 patients received compensation for a patient injury. These
139 comprised 44.1% of all (136) compensated patient injuries in vascular surgery. Distribution of
140 compensated and non-compensated patient injury claims by the years is shown in Figure 1. A
141 typical patient was treated in a high-volume centre by a fully trained vascular surgeon (Table I).

142 The mean age of the patients was 67.0 years ± SD 8.7 (range 47 to 86 years) and 37 patients
143 (61.7%) were men. Patients' comorbidities are presented in Table II.

144 Twenty-six (43.3%) patients were treated for critical limb threatening ischemia (CLTI) and 34
145 (56.7%) for claudication. Of the injured patients, 45 (75.0 %) underwent open revascularisation
146 surgery. For eight (13.3%) patients, the injury occurred in conjunction with amputation and for
147 seven (11.7%) patients, injuries were related to an endovascular procedure. Types of operation
148 are listed in Table III.

149 Incidents leading to injury classified by a care-flow basis are presented in Table IV. For 9
150 patients, two separate injury mechanisms were identified. Sixty-nine patient injury incidents
151 were recorded in 60 patients.

152 *A. Outpatient and preoperative care*

153 Sixteen injuries (23.2%) were related to either outpatient or preoperative care. Two patients
154 suffering from critical limb threatening ischemia were first incorrectly treated for sciatic nerve
155 pain. Four patients had been referred to a vascular surgeon but had experienced significant
156 delays in arterial imaging. Five patients had to wait too long for an operation or thrombolysis due
157 to the unavailability of proper operating theatre or operator. In other five patients the injury
158 incidents were not directly related to vascular surgery. The incidents ranged from problems in
159 preoperative catheterisation to missed lung cancer in preoperative imaging.

160 *B. Operative care*

161 A total of 27 injuries (39.1%) were caused by incidents during operative care. Three out of four
162 nerve injuries concerned the femoral nerve and one the peroneal nerve. Two (3.3%) patients
163 experienced an injury to an adjacent organ; in one patient, the pancreas was injured, and in
164 another, the small bowel. Five (8.3%) patients received skin burns during operations, either from
165 an incorrectly positioned patient return electrode or hot gauzes. Four (6.7%) patients were

affected by technical errors in creating a bypass such as graft kinking or creating distal anastomosis in a vein instead of artery.

For two (3.3%) patients, the chosen method of operation was considered poorly chosen. In one patient a femoral endarterectomy was estimated to have been sufficient to alleviate the patient's claudication and the performed femoropopliteal bypass was considered unnecessary. In other patient an angiography was performed in both legs even though only one leg was symptomatic.

Retained foreign material caused injuries to four (6.7%) patients. Retained gauze in two amputation wounds and one in an abdominal cavity were found to be the causes of injury for three patients. In one operation a dilatation balloon broke during a procedure and part of the broken catheter was left unnoticed in the artery. Incorrect medication during a procedure affected 1 (1.7%) patient. The patient received a heparin infusion instead of a urokinase infusion during thrombolysis.

C. Postoperative care

A total of 26 injuries (37.7%) were related to postoperative care. Five (8.3%) patients suffered from postoperative haemorrhage. Eleven (18.3%) patients had a postoperative infection. Of these patients four had infection of the Y-prosthesis, 5 of femoropopliteal or femorotibial prostheses, 1 of femoral patch, and 1 of teflon reinforcement patch in bypass.

Four (6.7%) patients received either an insufficient or incorrect medication postoperatively.

D. Consequences of the injuries

The consequences of the injuries ranged from inconvenience and extra hospital visits to prolonged hospital stay, permanent disability, and death. Experts evaluated that delay in treatment preoperatively caused two major amputations. These both involved patients who had already been referred to vascular surgeon and were waiting for preoperative imaging. While they waited the critical limb threatening ischemia situation worsened and eventually left no other

choice than amputation for treatment. Patients who had been first treated for sciatic nerve pain were treated successfully and the delay caused no other consequences but prolonged pain.

Intraoperative injury to the pancreas led to the partial removal of the pancreas and development of diabetes. Small bowel injury required a bowel resection. One of the femoral nerve injuries was temporary. Three other nerve injuries led to permanent disability and to significant pain and loss of function. All burn injuries healed without operative intervention. Technical problems in bypass operations led to loss of the graft and to re-operation.

Two patients suffered from an incorrect choice of operation method. Creating a bypass instead of only doing a femoral endarterectomy led to a bypass occlusion and to several re-operations. The changes in the arteries were considered such that indication for bypass did not exist. In the other patient, angiography had only been planned to one leg. Mistakenly it was performed to both legs and it led to graft thrombosis and bypass re-operation in the originally asymptomatic leg. Three of the retained foreign bodies led to re-operation, and one caused a delay in wound healing.

The incorrect antithrombotic medication during thrombolysis lead to large haematomas, which healed without intervention. One deep vein thrombosis and one stroke were considered to be caused by lack of adequate postoperative antithrombotic medication. One patient received a triple dose of antibiotics, but this led to no permanent harm. Another patient received only a short course of intravenous antibiotic because a positive blood culture result was missed. This led to temporary worsening of the patient's infection.

Postoperative haemorrhage lead to re-operation in 4 patients. One (1.7%) patient died at home 5 days postoperatively of haemorrhage after femoral endarterectomy. The death was deemed a patient injury because it was considered an unreasonable consequence of treatment. No fault was found in the patient's treatment. There were no other deaths compensated as "patient injury" in our dataset.

Infections were considered patient injuries in case they caused unreasonable consequences to the patient and the patient's risk of infection preoperatively was considered low. Postoperative infections occurred mostly within days or weeks of the original operations. Infections of the Y-prosthesis were an exception as 3 out of 4 of the infections occurred years after the original operation. Removal of infected prosthetic graft material was necessary for 9 (15.0%) patients. One infection of Y-prosthesis was treated with lifelong antibiotics.

4. Discussion

This is a comprehensive study of data obtained from a European country (Finland). It details all of Finland's PAD related accepted patient injuries and their causes during the study period. Our data came directly from the PIC insurance chart registry, which is nationwide and highly representative. Such a cohesive archive of patient injuries is rare in many countries and the Finnish PIC registry offers a unique chance to obtain a deeper understanding of the subject.(15) PIC does not only keep a registry but also provides education to health care professionals about patient injuries. Information concerning patient injuries can be used to enhance patient safety and prevent future injuries.

A. Comparison with previous studies

In our dataset, 44.1% of accepted claims in vascular surgery were related to PAD, which is a significantly higher percentage than in Sweden (23%) and the UK (21%). In our data only PAD patients are included in this percentage but in Sweden and UK other peripheral vascular conditions (e.g. aneurysms and emboli) are also implied.(13, 14) It should be observed that in Sweden a similar patient insurance system to Finland is in use. The main difference is that in Sweden no mistake or neglect needs to be shown. In UK the system is based on litigation claims by lawyers against the health care provider. This might affect the claims and compensations.

In patient injuries it is important to distinguish between actual injuries that result from normal risks associated with the disease itself and the treatment of PAD. Not all complications are

considered patient injuries, only the bodily injuries that fulfil the conditions prescribed in the Finnish Patient Injuries Act.(15)

Eleven patients received compensation for infection damage. When the original illness or injury that resulted in the infection is more serious the patient is expected to tolerate more serious consequences of an infection as well. If an infection injury has disproportionate consequences with the initial situation, it may be compensated in the unreasonable category.(15) 9 (81.8%) of the accepted infection claims involved a re-operation to remove infected prosthetic graft material.

The yearly percentage of compensated claims that involve PAD patients varied between 0-18.4% during our 14-year study period. No clear trend in injury numbers or types could be observed from the number of compensated cases. Similar variation in compensated cases has been seen in previous patient injury studies in otorhinolaryngology in Finland. (20) No clear difference could be observed between claims from different types of medical units.

The compensation percentage is clearly lower compared to previous patient injury studies in Finland. The percentage of all compensated patient injury claims was 27% in 2017.(15) In comparison, 43.6% of claims in total hip replacement surgery were compensated whereas in otorhinolaryngology the proportion was 26.1%.(21, 22) The majority of negative claim decisions are due to the experts' decision that the injury sustained could not be avoided despite the appropriate treatment the patient received.

A majority of accepted claims involved open surgery. In open revascularisations a 25.2% increase in number was evident from 2004 to 2017.(4) However, this does not seem to affect the amount of accepted claims, which had not significantly risen over the 14-year study period. Even though the number of performed endovascular procedures for PAD had grown by 28.8% from 2004 to 2017, only 11.7% of all accepted claims involved endovascular treatment. Increased endovascular operations seem to lead to patient injury only rarely. Similar results can also be

seen in Sweden where increasing number of endovascular procedures did not seem to influence the pattern of negligence claims.(23)

In 2004, 641 minor and 807 major lower limb amputations were recorded for PAD. In 2017, the corresponding values were 1314 and 863.(4) A rise in amputation numbers does not seem to correlate with a number of accepted claims. Only 13.3% of all accepted patient injury claims involved amputations.

The incidence of claims in Finland for all PAD related procedures including amputations in 2017 was 0.8%. The incidence ratio of the number of accepted claims to the number of procedures in 2017 was 1:1133. The yearly incidence of claims in a Swedish study was 0.14% and the corresponding incidence of accepted claims in peripheral vascular surgery per year was 1:2653.(13) Compared to Sweden the incidence of accepted patient injuries per procedure in our dataset was higher but patient injuries occurred only rarely.

The majority of injuries occurred during elective operations so they are not explained by limitations set by out of office hours. A similar trend can be seen in other studies as only 3.1-17.0% of the operations that led to injury were urgent.(13, 19, 24)

As much as 13.3% of the injuries occurred during operations performed by vascular surgeons in training. In other studies, 3.0-10.3% of the injuries were caused by trainees.(19, 24) Even though the percentage in our study is slightly higher, the relative inexperience of trainees seems to have only a minor role in explaining the injuries. Moreover, all of the revascularisation operations by trainees in our study were performed under supervision, although some amputations were performed unsupervised.

PAD is the third leading cause of atherosclerotic cardiovascular morbidity, following coronary artery disease and stroke.(25) A typical comorbidity profile of a PAD patient was also evident in our study. PAD is associated with more than a doubling of the 10-year rate of coronary events,

cardiovascular mortality, and total mortality.(26) Even with the best possible treatment, within 12 months of diagnosis 30% of CLTI patients will require an amputation and 25% will die.(27)

The most common cause for compensation in the UK was delay in the treatment or diagnosis (48%).(14) In our study, a total of 11 (18.3%) patients received compensation due to delays in diagnoses or treatments, and two major amputations were evaluated to be caused by delays. No national guideline in Finland exists to evaluate acceptable delays in treatment in vascular surgery but experts reviewed all cases and concluded that the prolonged waiting time had had a negative effect on patients' treatment and therefore compensation was in order. In Sweden, the most common reason for compensation after lower limb revascularisation was postoperative nerve injury (17.8%).(13) Other reasons included infection and graft occlusion.(13) In our study, there was a significantly lower proportion (6.7%) of compensated nerve injuries.

In Sweden, 3 deaths were compensated as a patient injury in the 2002–2007 period. The deaths comprised 6.7% of all compensated peripheral vascular disease injuries during that period. All deaths were related to endovascular care.(13) In our study, only one death was associated with patient injury and it involved open surgery. In some cases an injury may become eligible for compensation when the injury was evaluated as having had an unreasonable consequence for the patient.(15) In our dataset, a patient's death due to postoperative haemorrhage was compensated based on this criterion.

During the study period there were four cases of retained foreign material, which involved 6.7% of our study patients. In previous surgical malpractice claim studies, 3% of the injuries involved retained foreign material.(24) No cases of wrong site surgery were among the compensated injuries. These both are preventable injuries and are referred to as "never events". Tools such as the "WHO surgical checklist" have been developed to prevent never events and are nowadays mandatory in many countries including Finland.(19, 28)

B. Study limitations

Closed claim analysis has some limitations: Underreporting and inadequate knowledge about the insurance system might influence the claim frequency. PAD patients are usually elderly, have many comorbidities and might not therefore seek compensation from patient insurance even after experiencing an injury. It is important to understand that the PIC registry is not a registry of all complications in vascular surgery in Finland but only of cases for which the patient filed a claim for a suspected patient injury. On the other hand, the PIC registry covers the whole of Finland and is therefore highly representative of the country's patient injuries.

5. Conclusions

Compensated patient injuries in treatment of PAD are rare considering the numbers of patients treated. Injuries were identifiable during all stages of care. Most compensated claims in our study were associated with open surgical procedures. Injuries were caused by surgical process procedural causes and by familiar complications. Delays in treatment were also noted.

The Finnish patient insurance system was implemented to provide fair compensation to the patient and to facilitate the healthcare system in the provision of better patient care. Research and understanding the underlying patterns behind patient injuries in vascular surgery offers a valuable tool for improving quality and preventing future patient injuries in patient care. Future research is needed in the field.

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398 Figure legends:

399 Figure 1. The numbers (N) of peripheral arterial disease-related patient injury claims and
400 approved compensated claims by year (2004-2017). There were 625 claims in total over the 14-
401 year period of which 60 (9. 6%) claims depicted by orange bars were compensated as patient
402 injuries.

403

404 Table I. Characteristics of health care providers and operations in 60 patients with 69 patient
405 injuries in treatment of peripheral arterial disease from 2004 to 2017 inclusive.

		N	%
Medical Unit			
	University hospital	35	58.3
	Central hospital	22	36.7
	Local hospital	3	5.0
Specialization and training status of physician			
	Vascular surgeon	52	86.7
	Vascular surgeon in training	8	13.3
Operation type	Urgent operation	20	33.3
	Elective operation	40	66.7

406 N= Number, % = proportion of 69 patient injuries

407

408 Table II. Comorbidities of 60 patients with 69 peripheral arterial disease-related patient injuries.

	N	%
CAD	22	36.7
Hypercholesterolemia	27	45.0
Hypertension	43	71.7
Diabetes type I	3	5.0
Diabetes type II	21	35.0
Asthma/COPD	11	18.3
Rheumatoid disease	7	11.7
Hypothyreosis	5	8.3
Atrial fibrillation	6	10.0
Current smoker	32	53.3

409 N= Number, % = proportion of patient injuries, CAD= coronary artery disease, COPD = chronic

410 obstructive pulmonary disease

411

412 Table III. Main operations in 60 patients with 69 peripheral arterial disease-related patient
413 injuries from 2004 to 2017 inclusive.

Type of operation	N	%
Femoral exploration	1	1.7
Femoral endarterectomy	6	10.0
Femoropopliteal/tibial bypass with prosthesis	14	23.3
Femoropopliteal/tibial bypass with autologous vein	13	21.7
Aortoiliac/femoral bypass with prosthesis	10	16.7
Iliofemoral bypass with prosthesis	1	1.7
Diagnostic angiography	2	3.3
Angiography and angioplasty	4	6.7
Angiography and thrombolysis	1	1.7
Amputation toe	3	5.0
Amputation metatarsal	1	1.7
Amputation crural	1	1.7
Amputation femoral	3	5.0
Total	60	100

414 N=number, %=proportion of patient injuries

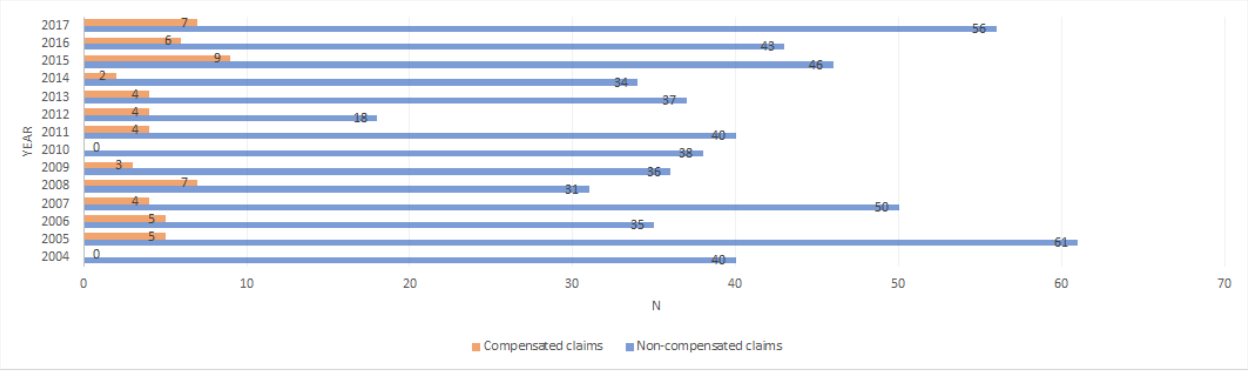
415

416 Table IV. Incidents and errors leading to 69 peripheral artery disease-related patient injury
417 classified by a patient care-flow basis of 60 patients.

	Incident 1		Incident 2	
	N	%	N	%
OUTPATIENT CARE				
Delay or error in diagnosis or treatment	4	5.8		
Injury in surgical outpatient procedures	0			
Other error in outpatient care	0			
OPERATIVE UNIT				
Preoperative period				
Incorrect/unnecessary procedure or technique	2	2.9		
Other error in preoperative care	3	4.3		
Delay in preoperative care	7	10.1		
Operative care				
No prophylactic antibiotic	0			
Problems in anaesthesia procedures	2	2.9		
Wrong site surgery	0			
Nerve lesion	4	5.8		

Other injury to adjacent anatomical structure	2	2.9		
Skin burns	5	7.2		
Other errors in surgical technique	7	10.1		
Haemostatic problem	0			
Retained gauze/instrument	4	5.8		
Equipment-related errors	1	1.4		
Charts or instructions insufficient	0		1	1.4
Other error in procedure	1	1.4		
Postoperative period				
Postoperative ward care	2	2.9		
Wrong/insufficient medication	4	5.8		
Infection	7	10.1	4	5.8
Haemorrhage	3	4.3	2	2.9
Postoperative treatment/control insufficient	2	2.9	2	2.9
Retained foreign body	0			
Unintended result	0			

418 N=number, %=proportion



Compensated patient injuries in the treatment of PAD are rare.

PAD patient injuries occur during all stages of care.

PAD patient injuries are caused both by systemic causes and common complications.